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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,230	01/02/2004	Jinbo Xu	GLH 08-896943	1114
27667 7590 07/25/2008 HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718				
EXAMINER BORIN, MICHAEL L				
ART UNIT 1631		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/751,230

Applicant(s)

XU ET AL.

Examiner

Michael Borin

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Amendment filed 04/28/2008 is acknowledged. Claims 1-11,13,15 are pending. Claim 1 is amended.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11,13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is necessitated by amendments and is applied for the following reasons:

- B. Claims 1 introduces new matter as it recites that optimally aligned structure is identified and output as "the best fit".

First, with respect to a structure being output, specification does not teach outputting a best aligned structure. Rather, specification addresses obtaining an energy score as the last method step – see p. 15, lines 15-20 and Fig. 6. There is no disclosure of a structure being output.

Second, with respect to “best fit”, although specification discloses how to perform method steps (Fig. 6, for example), it does not disclose that a performing these steps results in identifying a “best fit”.

Response to arguments

Applicant addresses “new matter” rejection made under 35 U.S.C. 112, first paragraph, as if it was an indefiniteness rejection made under 35 U.S.C. 112, second paragraph. See response filed 04/28/2008, p. 6, lines 13-14. The rejection, however, addresses “new matter” introduced by claim amendments, rather than indefiniteness of claim language.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-11,13,15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a computer process of aligning query protein sequence with protein structures. The method includes computational steps of selecting functions and constraints, and performing linear programming analysis. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

To be statutory, an invention must be directed to one of statutory categories enumerated in 35 USC § 101, or must produce a result which is useful, and tangible, and concrete. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the computational steps to produce a real-world result. The last recited step of the method of the amended claim 1 is outputting the structure that optimally aligns as the best fit (for claim 15 the output is an energy score). However, as the claim does not specify the nature of the

"output" it encompasses outputting result in a form not immediately available to a user, e.g., to internal memory of a computer. This may take entirely within the confines of a computer or human mind without any communication to the outside world. In addition, being output might mean being output to Internet via carrier waves (see p. 22, lines 19,20) " is being reads on carrier waves, which cause said claims to being drawn to non-statutory subject matter. A claim must be limited only to statutory embodiments - thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

To overcome the rejection, the claims may be amended to recite tangible output (e.g., displaying, etc.) or a subsequent physical transformation.

Furthermore, in regard to claim 15, "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, also clarifies that claiming non-statutory subject matter on a computer system or medium or in software does not prevent this rejection.

Response to argument

Applicant argues that amendment of the claim to recite that the structure that optimally aligns as the best fit is being output overcomes the rejection. However, as the claim does not specify the nature of the "output" it encompasses outputting result in a form not immediately available to a user, e.g., to internal memory of a computer. This may take entirely within the confines of a computer or human mind without any

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communication to the outside world. A claim must be limited only to statutory embodiments - thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,2,15 are rejected under 35 U.S.C. 102(b) as anticipated by Meller et al (Meller et al. Proteins: Structure, Function, and Genetics, 2001, Volume 45, Issue 3 , Pages 241 – 261).

The instant claims are drawn to method of aligning a query protein sequence with a template comprising a set of pre-selected protein structures in a database, comprising the steps of:

- selecting an energy function, said energy function being a linear combination of energy parameters, with weight factors as coefficients;
- establishing linear programming (LP) constraints for threading (or aligning) said query protein sequence with each structure in said set of pre-selected protein structures in a database;

- and performing a linear programming analysis based on a linear programming formulation including said energy function under said constraints,
- to optimally align said query protein with said template,
- the structure of the template that optimally aligns with the query protein sequence identified as the best fit.

Meller et al teach scoring method for sequence-to-structure alignments with parameters optimized by linear programming (LP). The method comprises steps of

- selecting an energy functions including energy parameters and weighting factors, determining values for weighting factors in said energy function (see pp. 242-244),
- using linear programming (LP) to identify constraints for threading. p. 243, right column through p. 244, left column, Table II, or p. 245, right column, or p. 248, left column last line.
- Performing linear programming on training sets of proteins (viewed as templates) - see, for example, p. 244, left column, pages 245-246.
- Performing threading to optimally align query protein. p. 251-255

Response to arguments

Applicant repeatedly acknowledges that Meller et al describe use of linear programming and threading but argues that the referenced method does not perform threading using linear programming. However, as argued previously, the instant claims while stating establishing LP constraints for threading (which Meller reference does as

well), do not explicitly state using LP for threading itself. The language "performing linear programming analysis" does not mean that threading itself is done using LP.

Further, the claims use open-ended language "comprising", and as such, may encompass any other steps, such as using dynamic programming addressed in the reference.

5. Claims 3-7,11,13 are rejected under 35 U.S.C. 103(a) as obvious over Meller et al in view of Akutsu et al. in view of Akutsu et al. (On the Approximation of Protein Threading. RECOMB, 1997, p. 3-8)

The reference of Meller et al is applied as above.

With respect to claims 3-7,11,13 if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various limitations of linear programming analysis and graph analysis, it would be conventional and within the skill of the art to select and/or determine such conditions as their selection for the intended purpose of obtaining successful protein threading algorithm is well known in the art; and the selection of appropriate parameters for linear programming is conventional and within the skill in the art to which this invention pertains. See Akutsu et al, for example.

Response to arguments

Applicant argues that Akutsu reference does not remedy the deficiency of Meller with regard to use of LP for threading. This issue is addressed above in discussing rejection under 35 U.S.C. 102(b).

Conclusion.

6. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./

Primary Examiner, Art Unit 1631